IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., a Japanese company; Plaintiff, v. SAREPTA THERAPEUTICS, INC., a Delaware corporation Defendant.	CIVIL ACTION NO. _____ [redacted] Public Version Filed July 20, 2021

NIPPON SHINYAKU'S MEMORANDUM IN SUPPORT OF ITS MOTION FOR PRELIMINARY INJUNCTION

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I. INTRODUCTION

On June 21, 2021, Defendant Sarepta Therapeutics, Inc. ("Sarepta") [redacted] filing seven petitions for *inter partes* review ("IPR") of Nippon Shinyaku's U.S. Patent Nos. 9,708,361; 10,385,092; 10,407,461; 10,487,106; 10,647,741; 10,662,217; and 10,683,322 (collectively, the "NS Patents") before the Patent Trial and Appeal Board ("PTAB") (hereinafter referred to as "IPR Petitions").[1] [redacted].

As such, Nippon Shinyaku seeks a preliminary injunction requiring that Sarepta immediately withdraw its IPR Petitions. As described more fully below, Nippon Shinyaku's right to relief is indisputable. Sarepta [redacted]

[1] These seven IPR Petitions were filed with the following case numbers: (i) IPR2021-01134; (ii) IPR2021-01135; (iii) IPR2021-01136; (iv) IPR2021-01137; (v) IPR2021-01138; (vi) IPR2021-01139; and (vii) IPR2021-01140.

II. STATEMENT OF FACTS

A. The Parties

Nippon Shinyaku is an innovative pharmaceutical company headquartered in Kyoto, Japan whose mission is to "help people lead healthier, happier lives." It achieves this mission by developing and supplying unique and high-quality therapies that are both safe and highly effective relative to other drugs and contribute to a better quality of life for patients. This includes providing meaningful relief to patients suffering from rare, intractable diseases, such as Duchenne Muscular Dystrophy ("DMD")—a severe X chromosome-linked genetic disorder predominantly affecting young boys. Children with DMD suffer from muscle weakness as early as age four and progressively lose function and quality-of-life such that by age twelve, DMD patients typically lose ambulatory function and are confined to wheelchairs. Most patients suffering from DMD do not live past their twenties.

Recognizing the severe impact of DMD, Nippon Shinyaku developed VILTEPSO® to treat DMD patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping.[2] On August 12, 2020, the Food and Drug Administration ("FDA") granted accelerated approval to VILTEPSO®.[3] As the FDA noted, it approved VILTEPSO® under the accelerated approval pathway, "which provides for the approval of drugs that treat serious or life-threatening diseases and generally offer a meaningful advantage over existing treatments."[4]

Sarepta is a Delaware corporation with its principal place of business in Cambridge, Massachusetts that also develops treatments for DMD. On December 12, 2019, FDA granted

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2 *See* Complaint filed concurrently at ¶¶ 27-29 for further description of exon 53 skipping.

3 *See* https://www.fda.gov/news-events/press-announcements/fda-approves-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last accessed July 9, 2021).

4 *Id.*

Sarepta accelerated approval for VYONDYS 53—Sarepta's DMD treatment for patients who have a confirmed mutation of the dystrophin gene that is amenable to exon 53 skipping.[5]

B. The Parties' [redacted]

Nippon Shinyaku and Sarepta [redacted][7] [redacted][8] [redacted][9] [redacted][10] Neither Nippon Shinyaku nor Sarepta

[5] *See* https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-first-targeted-treatment-rare-duchenne-muscular-dystrophy-mutation (last accessed July 9, 2021).
[6] Ex. A at 1.
[7] *Id*. at § 10 (emphasis added).
[8] *Id*. at 2 (emphasis added).
[9] *Id*. at 2.
[10] *Id*. at § 7.

[redacted]

[redacted].

C. Sarepta's Filing of Petitions for *Inter Partes* Review of Nippon Shinyaku's Patents

[redacted][11] [redacted]

[redacted].[12] [redacted] NS Patents, each of which concerns the Parties' development and commercialization of therapies for DMD.

D. Nippon's Letter to Sarepta Regarding Sarepta's [redacted]

Nippon sought to resolve this dispute amicably and without judicial intervention. On June 24, 2021, [redacted] On June 30, 2021, [redacted]

[11] *Id*. at § 10.
[12] *Id*. at 2.

III. NIPPON SHINYAKU IS ENTITLED TO A PRELIMINARY INJUNCTION

A. Preliminary Injunction Standard

"A plaintiff seeking a preliminary injunction must establish that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor, and that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). A movant for preliminary equitable relief "must meet the threshold for the first two 'most critical' factors: it must demonstrate that it can win on the merits (which requires a showing significantly better than negligible but not necessarily more likely than not) and that it is more likely than not to suffer irreparable harm in the absence of preliminary relief. If these gateway factors are met, a court then considers the remaining two factors and determines in its sound discretion if all four factors, taken together, balance in favor of granting the requested preliminary relief." *Reilly v. City of Harrisburg*, 858 F.3d 173, 179 (3d Cir. 2017), as amended (June 26, 2017).

"An injunction is 'mandatory' if such an injunction would 'alter the status quo by commanding some positive act.'" *Doe v. Delaware State Univ. Bd. of Trustees*, No. C.A. 20-1559 (MN), 2021 WL 2036670, at *2 (D. Del. May 21, 2021). "When seeking a mandatory injunction, the burden on the moving party is 'particularly heavy,' and the movant's right to relief must be 'indisputably clear.'" *Id.*

B. Nippon Shinyaku is Likely to Show that Sarepta's [redacted]

Nippon Shinyaku is likely to succeed on the merits of its breach of contract claim against Sarepta. In Delaware, a breach of contract claim requires the plaintiff to establish "(1) the existence of a contract; (2) the breach of an obligation imposed by the contract; and (3) resulting damage to the plaintiff." *Cipla Ltd. v. Amgen Inc.*, 386 F. Supp. 3d 386, 394 (D. Del. 2019).

First, there is no dispute that [redacted].

Second, [redacted]

[redacted][13]

As the Delaware Supreme Court has explained, [redacted] *Ingres Corp. v. CA, Inc.*, 8 A.3d 1143, 1145-1146 (Del. 2010). Thus, [redacted].

[redacted]

[redacted]

[13] Ex. A at § 10 (emphasis added).

[redacted][14]

The IPR Petitions are patent disputes between Nippon Shinyaku and Sarepta in connection with the Parties' development and commercialization of therapies for DMD, as they directly challenge the validity of Nippon Shinyaku's patents relating to therapies for DMD. Moreover, the PTAB is as an administrative agency, as it is an administrative adjudicatory body in the United States Patent and Trademark Office. *See, e.g.*, *United States v. Arthrex, Inc.*, 141 S. Ct. 1970 (2021).

Sarepta was [redacted]

Third, [redacted]

Thus, for all of the above reasons, it is clear that Nippon Shinyaku is likely to succeed on the merits of its breach of contract claim against Sarepta.

C. Nippon Shinyaku Will Suffer Irreparable Harm Absent Relief

"In order to demonstrate irreparable harm[,] the plaintiff must demonstrate potential harm which cannot be redressed by a legal or an equitable remedy following a trial. The preliminary injunction must be the only way of protecting the plaintiff from harm. The requisite feared injury or harm must be irreparable—not merely serious or substantial, and it must be of a peculiar nature, so that compensation in money cannot atone for it." *Kamdem-Ouaffo v. Task Mgmt. Inc*, 792 F. App'x 218, 221 (3d Cir. 2019) (internal citations omitted).

[14] *Id*. at 2 (emphasis added).

Nippon Shinyaku will be irreparably harmed if the injunction does not issue, as [redacted]. [redacted]

Indeed, [redacted] *BE & K Eng'g Co., LLC v. RockTenn CP, LLC*, No. CIV. A. 8837-VCL, 2014 WL 186835, at *23 (Del. Ch. Jan. 15, 2014), judgment entered 2014 WL 494345 (Del. Ch. Feb. 6, 2014), and *aff'd sub nom. RockTenn CP v. BE & K Eng'g Co., LLC*, 103 A.3d 512 (Del. 2014); *see also ASDC Holdings, LLC v. Richard J. Malouf 2008 All Smiles Grantor Retained Annuity Tr.*, No. CIV. A. 6562-VCP, 2011 WL 4552508, at *8 (Del. Ch. Sept. 14, 2011) ("[T]he procession of a claim in an unwarranted forum poses a threat of irreparable harm warranting a preliminary injunction. To hold otherwise . . . would render the broad language of the [redacted] of the benefit of [its] bargain.").

Not only will Nippon Shinyaku suffer irreparable harm [redacted], but it also will suffer irreparable harm because it will be forced to litigate the issues of patent validity of its patents on multiple fronts with the possibility of inconsistent results. As laid out in the Complaint filed concurrently with this motion, Nippon Shinyaku asserts that Sarepta's VYONDYS 53 infringes

all of the NS IPR Patents except U.S. Patent No. 9,708,361.[15] Thus, it is inevitable that Sarepta will assert invalidity defenses regarding these patents before this Court. Ultimately, this requires Nippon Shinyaku to defend its patents' validity in multiple forums [redacted] Litigation of the patents' validity in multiple forums also runs the risk of yielding conflicting results, which would also serve to irreparably harm Nippon Shinyaku.

D. The Equities Heavily Favor [redacted]

The balance of equities also weighs in favor of Nippon Shinyaku. As discussed above, Nippon Shinyaku would suffer irreparable harm from [redacted] having to litigate the validity of its patents in two separate forums. Sarepta, however, would not suffer harm by [redacted]. Sarepta [redacted]

E. The Public Interest Weighs in Favor of Preliminary Relief

The public interest also weighs in favor of granting Nippon Shinyaku's preliminary injunction, as the public has an interest in enforcing contractual rights and obligations. Sarepta [redacted] "There is no public interest served by excusing a party's violation

[15] Compl. at ¶¶ 94, 106, 115, 126, 131-134, and 138-145.

of its previously negotiated contractual undertaking to litigate in a particular forum." *Gen. Protecht Grp., Inc. v. Leviton Mfg. Co.*, 651 F.3d 1355, 1366 (Fed. Cir. 2011).

IV. CONCLUSION

For these reasons, Nippon Shinyaku has demonstrated that its right to relief is indisputably clear, and Sarepta should be ordered to withdraw its IPR Petitions. *See, e.g.*, *Dodocase VR, Inc. v. MerchSource, LLC*, 767 Fed. Appx. 930 (Fed. Cir. 2019) (affirming district court's grant of preliminary injunction and ordering Defendant to withdraw its PTAB Petitions due to Defendant's breach of forum selection clause in parties' contract); *Nomadix, Inc. v. Guest-Tek Interactive Ent., Ltd.*, No. 19-04980, 2020 WL 1939826 (C.D. Cal. Apr. 22, 2020) (granting Plaintiff's permanent injunction due to Defendant's breach of the parties' forum selection clause by filing IPR petitions in the PTAB). Nippon Shinyaku thus respectfully requests the Court grant its Motion for a Preliminary Injunction and order Sarepta to withdraw its IPR Petitions.

Dated: July 13, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on July 12, 2021, I caused a copy of the foregoing document, the Complaint, and all documents associated with this Motion to be electronically mailed to Christopher Verni (cverni@sarepta.com), the Senior Vice President, Deputy General Counsel & Chief Intellectual Property Counsel of Defendant Sarepta Therapeutics, Inc.

/s/Amy M. Dudash
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